ISCD –NIST Workshop

Peripheral BMD Technologies

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Why Should the World Care About Peripheral BMD Technologies ?

- 1. Much of the world has little access to central DXA.
- 2. Peripheral devices have consistently been shown to predict an increase risk for fracture in multi-ethnic populations.
- 3. The WHO absolute fracture risk project is calculating risk with and without central DXA--appropriate since low BMI may substitute for central (femoral neck) BMD for risk assessment.
- 4. Yet, clinician's often want a “quantitative number” before starting treatment—peripheral BMD offers this for populations with no or limited access of central DXA.

Critical Challenges for ….

- Inconsistent young-normal reference population databases for comparison of T-scores between peripheral devices (or linked to central DXA devices)
- Inconsistent absolute units (BMD,BMC,SOS,BUA) linked to fracture risk between devices.
- Inability to use peripheral devices (with possible exception of forearm DXA) for WHO diagnosis
- Inability to use peripheral devices for monitoring
- No clinical trial data linking low BMD randomization criteria to clinical outcomes with pharmacological therapy

Clinical Application of Bone Densitometry

- Diagnosis of Osteoporosis (WHO Criteria)
- Fracture Risk Prediction
- Monitoring of Disease States that Effect Bone and/or Pharmacological Effect of Bone-Active Agents

Can Peripheral Devices be used for Monitoring?

NO

Why?

- 1. The precision error of peripheral devices as good as central devices
- 2. For unknown reasons current osteoporosis therapies do not influence measurable changes in peripheral devices (DXA and/or US).
- 3. Forearm DXA may be an exception (increases with HT and decreases with PTH)

Can Peripheral Devices Be Used for WHO Classification? : NO!

- 1. WHO classification linked prevalence (based on central and forearm DXA) to lifetime fracture risk
- 2. Different (inconsistent) young-normal reference population databases from which the T-score is calculated exist between devices
- 3. Forearm DXA might be an exception

WHY THE WHO CHOSE T = -2.5

"Such a cutoff value identifies approximately 30% of postmenopausal women as having osteoporosis using measurements made at the spine, hip, or forearm. This is approximately equivalent to the lifetime risk of fracture at these sites."

Kanis JA, et al. *J Bone Miner Res* 1994; 9:1137

Potential Explanations for Discrepancies

- Database differences (means, SD)
- Technical variations
- Regional differences in rates and times of bone loss

Small Differences in the SD of BMD between 2 healthy, yet dissimilar young-normal reference populations

Can Profoundly effect the subsequent T score calculation of any given patient

Faulkner K, et al J Clin Densit 1999; 2: 343

Can “Peripheral Devices”

Predict Either Global (non-site-specific) or Site-Specific Fracture Risk?

YES

Comparing Risk Prediction Between Peripheral and Central

If The Under-Detection Issues by peripheral devices are not resolved:

Risk Prediction by Peripheral Devices will also be underestimated

Inconsistency in Bone Mass Measurement Measurements: I

- 1. WHO diagnostic criteria can only be applied using central DXA (spine and hip) and possibly forearm (if the ROI and database from that the BMC and/or T-score is defined is similar to the units used in 1992 to define the WHO criteria).
- 2. Other peripheral technologies cannot be used for WHO diagnosis without a consistent reference population database is established linking that database-derived T or Z scores to population-based global fracture risk-or….
- 3. Device-specific cut-points are established with each specific peripheral device using that device reference population database T-score that matches the equal T-score which predicts risk by the central device.

Inconsistency in Bone Mass Measurement Measurements: II

- 4. Peripheral technologies (both DXA and QUS) can be used for site-specific or global fracture risk prediction though each manufacturer units of measurement (T-score from each manufacturer-specific reference population database or absolute units of SOS/BUA deviation from a specific population-based mean) differs from device to device.

- 5. Implementation of peripheral technology nation to nation for fracture risk prediction does not require establishing a nation specific reference population database if absolute units of SOS/BUA are used for the measurement.

- 6. Implementation, however, does require that a specific nationality define the population mean absolute SOS/BUA units (mean age 60 yrs) for each manufacturer device.

Conclusions

- T-scores < 1.0 by peripheral technologies are associated with increased fracture risk.
- T-scores < - 1.8 using peripheral devices are associated with a much higher fracture risk than T-scores > -1.8.
- Peripheral devices have not been used in the randomization for evidence of efficacy in clinical trials—so it is unknown if current pharmacological therapies for osteoporosis will reduce fracture risk based on peripheral device derived T-scores

Conclusion

Nevertheless, for much of the world, the finding of a low T-score or deviation of an absolute value from the population-derived mean by a peripheral device can be used to assess risk